LABORATORY GUIDANCE

The Missouri Department of Agriculture anticipates significant program modifications by the end of 2020 in order to comply with federal law. Modifications may include procedures outlined in this document.

The following section is intended for Registered Producers.

Registered Producers are responsible for selecting a laboratory that meets all accreditation, registration, testing, and reporting requirements. *Compliance of lots may be invalidated if a laboratory is found to not meet all requirements.*

LABORATORY QUALIFICATIONS

- Registered with the Drug Enforcement Agency (DEA) or other requirements established by the United States
 Department of Agriculture; or
- Accredited to International Organization for Standardization for ISO/IEC 17025

A list of DEA registered laboratories is available at https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories. There is not currently a comprehensive list available for ISO 17025 accredited laboratories, but labs will often have their accreditation status posted online or available upon request.

Please note that on February 27, 2020, USDA <u>made an announcement</u> related to the requirement that all U.S. hemp producers must utilize DEA-registered testing laboratories. This announcement does not change Missouri industrial hemp rules, and registered producers in Missouri are required to select a qualifying laboratory as listed above.

COMPLIANCE DETERMINATION

Most laboratories will include a "pass" or "fail" determination on the certificate of analysis; this determination is based on the total THC measurement and the measurement of uncertainty (MU) calculated by the laboratory. If there is no MU calculated or present on the certificate of analysis, the MU is 0.000%.

For example, if the total THC measurement is 0.32% but the MU is calculated at 0.028%, then the range created is 0.292% - 0.348%. This sample is compliant (pass) because the range contains or is below the 0.3% acceptable THC level.

SUBMITTING CERTIFICATES OF ANALYSIS

Registered producers must submit certificates of analysis for all samples used to determine compliance to the department via email to reporting.hemp@mda.mo.gov.

- For certificates of analysis that "pass" or demonstrate compliance, registered producers must submit a copy to the department within **thirty (30) business days** of receipt of results
- For certificates of analysis that "fail" or demonstrate non-compliance, or for any retest, registered producers must submit a copy to the department within **three (3) business days** of receipt of results

RETESTING

If the initial test indicates a "fail", the Registered Producer must submit the results as detailed above, and concurrently notify MDA of the intent to retest, if applicable. If requested by the producer, the laboratory may retest the 'retain specimen' already in their possession, as indicated in Steps 7 and 8 of the laboratory procedures section of this document. All retest certificates of analysis, regardless of results, must be submitted within three (3) business days. The duplicate sample retained by the Registered Producer or Certified Sampler cannot be utilized for retest purposes.

LABORATORY GUIDANCE



The following section is intended for laboratory personnel.

LABORATORY PROCEDURES

These procedures are intended as guidelines for laboratories conducting compliance testing for hemp, and are based on those outlined in USDA Interim Final Rule; listed in 7 CFR Part 990 [Doc. No. AMS—SC—19—0042; SC19—990—2 IR] https://www.govinfo.gov/content/pkg/FR-2019-10-31/pdf/2019-23749.pdf

- 1. All equipment utilized throughout the testing process must be adequately cleaned between each sample to prevent contamination and carryover.
- 2. Immediately evaluate the security seal and Chain of Custody paperwork to ensure validity.
- 3. Assess the quality of the delivered sample. If the sample's quality is not sufficient for testing, immediately notify the producer so that they may take additional action.
- 4. Promptly dry the plant material in a manner consistent with maintaining quality, including cannabinoid content, of the sample.
- 5. Homogenize the sample. This may be accomplished by pulverizing, grinding, or milling all cuttings.
- 6. Sieve the plant material through a screen no larger than 1.5 x 1.5 mm.
- 7. From the homogenized sample, obtain a "test specimen" and "retain specimen" consisting of the quantity necessary to conduct appropriate testing. Any surplus material may be properly disposed of.
- 8. The "retain specimen" must be packaged, security sealed, and stored in a secured place in a manner consistent with maintaining quality of the sample, including cannabinoid content. This retained specimen may be tested if requested by the producer.
 - a. The retained specimen must be preserved for an established, published period after the "test specimen" testing is completed. MDA recommends fifteen (15) days, but yields to laboratory business practices.
- 9. The specimen(s) must be tested for Delta-9 tetrahydrocannabinol (THC) <u>post-decarboxylation</u>, or other similarly reliable methods approved by the United States Department of Agriculture that account for the <u>Total THC</u>, including a calculated value using Delta-9 THC plus 87.7% of THC-A.

INCREASED SAMPLE SIZE

Each sample will contain a minimum of one (1) cutting and up to a maximum of one-hundred fifty (150) cuttings per lot, with three (3) to six (6) cuttings being most common. The quantity collected depends on many factors including the overall lot size and the option to split samples to create a duplicate 'backup' sample. Each cutting will contain approximately twenty centimeters (20cm) of plant material, or the entire inflorescence of the branch it was taken from. The program understands this amount of plant material is significantly more than what is required to conduct testing and may create a strain on laboratories. However, the increased sample size is pertinent to develop a truly representative sample and reduce sampling error. Once homogenization is completed, laboratories may separate the amount needed to create the specimens outlined in Steps 7 and 8 above, and properly dispose of any surplus material.

MEASUREMENT OF UNCERTAINTY

A Measurement of Uncertainty (MU) is the parameter, associated with the result of a measurement, which characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement. It is a laboratory-calculated measurement that is similar to a margin of error. *If no MU is calculated or presented on the certificate of analysis, the MU is effectively 0.000%.* Additional information about Measurement of Uncertainty can be found in the "Guidelines for Testing" document available through USDA at: https://www.ams.usda.gov/rules-regulations/hemp/information-laboratories

MISSOURI DEPARTMENT OF AGRICULTURE PLANT INDUSTRIES DIVISION INDUSTRIAL HEMP PROGRAM

LABORATORY GUIDANCE

CHAIN OF CUSTODY

All compliance samples from Missouri's registered producers must be in a *sealed* package, include a *signature* or initials from the registered producer **and** the Certified Sampler over the seal, and have a *Chain of Custody* form attached to each bag. The Chain of Custody form is available on the program website, in the Certified Samplers tab at: https://agriculture.mo.gov/plants/industrial-hemp/sample-chain-of-custody-form.pdf

The Chain of Custody form will include a *Sample ID*, which must be transcribed onto the Certificate of Analysis for further identification. The form will also include a list of transfers of possession, originating with the registered producer. The registered producer, the certified sampler, or their agent is permitted to deliver or ship the sample to the laboratory, with the Chain of Custody form updated and signed accordingly.

CERTIFICATE OF ANALYSIS

The following elements must be included on each compliance sample's Certificate of Analysis to ensure clear interpretation by all interested parties:

- Percentage content of tetrahydrocannabinol (THC)
 - Delta-9 THC measured post-decarboxylation; or
 - The calculated Total THC value using (Measured Delta-9 THC) + (Measured THC-A * 0.877)
- Clear declaration that decarboxylation methods were completed, if applicable
- Measurement of Uncertainty (MU), if calculated
- "Pass" or "Fail" determination
 - If the range created by the measurement of uncertainty contains or is below the acceptable hemp THC level of 0.3%, the sample is considered compliant and shall be labeled as "pass"
- Identifying information, including:
 - o Sample ID number (Ex: 29_R01930 A4 071819)
 - As identified on the Chain of Custody form; includes:
 - Producer registration (license) number
 - Lot ID
 - MMDDYY of sample collection
 - If not provided (such as for a non-compliance sample): the producer's name, registration (license) number, and contact information
 - Date test conducted
 - Laboratory name and contact information

REPORTING

For The Laboratory

USDA requires all laboratories to submit test results for all industrial hemp samples tested. More information about that reporting requirement can be found at: https://www.ams.usda.gov/rules-regulations/hemp/information-laboratories.

Missouri is currently operating under an extension of the 2014 Farm Bill. At this time, the Missouri Industrial Hemp Program does not have any additional reporting requirements for testing laboratories. However, laboratories that conduct testing for producers in other states should consult with applicable departments of agriculture prior to receiving samples from that state.

MISSOURI DEPARTMENT OF AGRICULTURE PLANT INDUSTRIES DIVISION INDUSTRIAL HEMP PROGRAM

LABORATORY GUIDANCE

REPORTING

On Behalf of the Producer

Registered producers are responsible for submitting certificates of analysis for all compliance samples to the department via email to reporting.hemp@mda.mo.gov. Laboratories may send these results on the producer's behalf, but it is the producer's responsibility to ensure receipt within the time guidelines. Any agreement to submit results on a producer's behalf is between the laboratory and the producer and is not regulated by the department.

Laboratory results submitted by the laboratory to the Missouri Department of Agriculture must include the **sample ID** number from the Chain of Custody Form.

- For certificates of analysis that "pass" or demonstrate compliance, a copy must be sent to the department within thirty (30) business days of the dissemination of results to the producer
- For certificates of analysis that "fail" or demonstrate non-compliance, a copy must be sent to the department within three (3) business days of the dissemination of results to the producer

CERTIFIED INDUSTRIAL HEMP SAMPLERS

Certified Industrial Hemp Samplers are authorized to collect compliance samples in accordance with the MDA Sampling Protocol, but may not collect compliance samples for registrations in their name, their employer's name, or for a registration in which they are a key participant.

Laboratory personnel are eligible to become Certified Industrial Hemp Samplers, and may do so as third-party individuals or as representatives of the laboratory.

More information about Certified Samplers and sampling can be found on our Certified Samplers webpage and in the MDA Sampling Protocol, both linked below.

https://agriculture.mo.gov/plants/industrial-hemp/certified-sampler.php https://agriculture.mo.gov/plants/industrial-hemp/sampling-protocol.pdf